PURDUE

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April 16, 2001

Via Federal Express

Charles J. Ganley, M.D.
Director, Division of OTC Drug Products, HFD-560
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857-1706

RE: Senna Carcinogenicity Study Update

Dear Dr. Ganley:

Reference is made to your letter of March 27, 2001 requesting an update on the progress of the 2-year rat carcinogenicity study currently being conducted on senna. The Oral Carcinogenicity Study of Senna, conducted by ClinTrials BioResearch, sponsored in collaboration by Novartis, Reckitt & Colman, Madaus AG, and Purdue Pharma L.P. was initiated in January 2000. The study is scheduled to be completed January 2002, pathology to be completed by September 2002, and an audited draft report expected October 2002. Submission of the study results to FDA should occur by the end of March 2003.

I hope this information satisfies your request and allows you to establish a timetable for completion of the Agency's rulemaking for OTC laxative drug products. Please do not hesitate to contact me for further information at (203) 588-8107 or Dr. Anthony Santopolo at (203) 588-7280.

Sincerely,

David W. Grob

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